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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,417	07/01/2003	Denis Leclerc	1398-104US	9472

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EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,417	LECLERC ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-42* is/are pending in the application.

4a) Of the above claim(s) *40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/8/05 and 8/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received October 12, 2005. The status of the claims is as follows:

Claims 20-42 are pending.

Claims 20-39 and 42 are under examination.

Claims 18, 19, 40 and 41 are withdrawn from consideration.

Election/Restrictions

Applicants' election of Group I and a viral antigen is acknowledged. Applicant argues the restriction requirement is improper because all the pending claims relate to the single concept of administering an antigen in combination with a specific adjuvant. However, this argument is not persuasive as restriction only requires a showing that the inventions are unrelated through different function or different modes of operation (see MPEP §§ 806.04 and 808.01). The Examiner respectfully submits that Inventions I-III have different functions because they are used to treat different populations. Thus, the inventions may be restricted for being unrelated.

Applicants further argue that the restriction requirement is improper because examination of the entire application would not create an undue burden. The Examiner respectfully disagrees. Inventions I-III are drawn to treating different populations, namely humans, fish and birds. Examining each of these inventions would require the Examiner to explore the differences between the immunology of these species. This would be required in order to determine whether or not the invention is enabled across the claimed species. Moreover, each species is susceptible to different pathogens and examination of all the claims could require a search of different

pathogenic antigens. For at least these reasons, examining the entire application would create a serious burden on the Examiner.

Applicants argue the restriction is improper because Group I is drawn to treating a human, yet the claims recite treating a mammal. This argument would be relevant if restriction were required between a human and a mammal. However, because a human is a mammal, the examination of Group I naturally includes treating a mammal as claimed.

Applicants argue that requiring restriction between the different species of pathogenic peptide as being unrelated is improper because the specification discloses that these species are capable of use together. Applicants point to language in the specification that says "one or more forms of an immunogen are coupled to one or more carrier VLPs . . . ." This argument is not persuasive because the cited language is not commensurate in scope with the claims. The specification generically states that multiple epitopes can be placed on the carrier virus. However, this does not indicate that the peptides claimed are capable of use together. That is, the specification does not indicate that viral, bacterial and parasitic antigens can be administered with a PapMV adjuvant.

Information Disclosure Statement

The information disclosure statements filed by Applicants have been signed and attached to this Office action. The references with a line drawn through them were not considered because they either (i) failed to include a statement of the relevance of a non-English document, or (ii) failed to include a copy of a non-patent document. Applicant is requested to correct these deficiencies if the references are to be made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-39 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is drawn to a method for "potentiatng an immune response . . . ." This language fails to define the scope of the invention to one skilled in the art. The skilled artisan would not understand whether claim 20 is drawn to inducing a cytokine response, a TH1 response, a TH2 response, an innate immune response, a mucosal immune response, or a systemic immune response. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-31, 33-39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention that is commensurate in scope with the claims without undue experimentation. Presently, the specification only enables inducing a humoral immune response in a mammal. The specification does not enable "potentiating an immune response" as claimed.

Undue experimentation is defined by the following factors: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Despite the lack of clarity noted above, the language "potentiating an immune response" allows the claims to read on many different aspects of the mammalian immune response. For example, the claims read on inducing mucosal immunity, as well as a TH2 cell-mediated response. The state of the art at the time this application was filed would not allow the skilled artisan to predict whether a PapMV-based adjuvant would induce these types of immunity. This results because research showed that using a plant virus as an antigen carrier produces a predominantly TH1 response. For example, fusing a variety of antigens to the cowpea mosaic virus was limited to producing a TH1 response as demonstrated by increased interferon gamma.[1] Moreover, inducing TH1 immunity is complicated by the fact TH1 cells are regulated by different members of different arms of the immune system.[2] This difficulty is apparent as research continues to present findings that contradict previously accepted theories on immunity.[3] Thus, using a PapMV adjuvant to induce the types of immunity claimed is an unpredictable science.

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[1] Brennan et al. Cowpea Mosaic Virus as a Vaccine Carrier of Heterologous Antigens *Molec. Biot.* 2001; 17:15-26

[2] Igietseme et al. "Antibody regulation of T-Cell immunity: implications for vaccine strategies against intracellular pathogens" *Exp Rev. Vaccines* 2004; 3, 1:23-34

[3] Gajewski et al. "'Anergy' of THO Helper T Lymphocytes Induces Downregulation of TH1Characteristics and a Transition to a TH2-like Phenotype" *J. Exp.Med.* 1994; 179:481-491

The difficulty of the types of immunity claimed by Applicants would require the skilled artisan to rely on the specification for reducing the invention to practice. However, the content of the specification only relates to using PapMV to induce TH2 (i.e. humoral) immunity. For example, Figure 7 only shows that a PapMV adjuvant can stimulate the production of immunoglobulin. Thus, the specification fails to provide adequate direction on how to regulate the types of immunity encompassed by the claims. As noted above the mechanism of TH1 regulation is complex and largely unknown. Thus, the skilled artisan would have to invest undue experimentation in order to practice the invention to induce the immune responses claimed.

Claims 20-31, 33-39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the present case, the claims are drawn to an adjuvant comprising "a virus-like particle . . . derived from [PapMV]." However, the specification only discloses the entire PapMV coat protein as having an adjuvant effect. The specification does not disclose any other PapMV proteins, or fragments of the coat protein, that are capable of enhancing an immunogenic response to an antigen. The specification similarly fails to describe any regions or sequences within the coat protein that are responsible for immunogenicity. Moreover, the antigenicity of PapMV was new in the art such that the skilled artisan was unaware of the peptides that were capable of inducing an immune response. Thus, the skilled artisan could not reasonably conclude that Applicants were in possession of an antigenic PapMV peptide besides the entire coat protein as set forth in the specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 11/28/05

TMB 11/24/05